# General

## Guideline Title

Clinical guidelines for diagnosis and treatment of lumbar disc herniation with radiculopathy.

## Bibliographic Source(s)

North American Spine Society (NASS). Clinical guidelines for diagnosis and treatment of lumbar disc herniation with radiculopathy. Burr Ridge (IL): North American Spine Society (NASS); 2012. 100 p. [446 references]

## Guideline Status

This is the current release of the guideline.

# Regulatory Alert

## FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines : A U.S. Food and Drug Administration (FDA) review has found that the growing combined used of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.
- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

# Recommendations

## Major Recommendations

The grades of recommendations (A–C, I) and levels of evidence (I–V) are defined at the end of the Major Recommendations field.

Recommendations for Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy

Diagnosis and Imaging

*What history and physical examination findings are consistent with the diagnosis of lumbar disc herniation with radiculopathy?*

Manual muscle testing, sensory testing, supine straight leg raise, Lasegue's sign and crossed Lasegue's sign are recommended for use in diagnosing lumbar disc herniation with radiculopathy.

*Grade of Recommendation: A*

The supine straight leg raise, as compared with the seated straight leg raise, is suggested for use in diagnosing lumbar disc herniation with radiculopathy.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against the use of the cough impulse test, Bell test, hyperextension test, femoral nerve stretch test, slump test, lumbar range of motion or absence of reflexes in diagnosing lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*What are the most appropriate diagnostic tests (including imaging and electrodiagnostics), and when are these tests indicated in the evaluation and treatment of lumbar disc herniation with radiculopathy?*

There is a relative paucity of high quality studies on advanced imaging in patients with lumbar disc herniation. It is the opinion of the work group that in patients with history and physical examination findings consistent with lumbar disc herniation with radiculopathy, magnetic resonance imaging (MRI) be considered as the most appropriate, noninvasive test to confirm the presence of lumbar disc herniation. In patients for whom MRI is either contraindicated or inconclusive, computed tomography (CT) or CT myelography are the next most appropriate tests to confirm the presence of lumbar disc herniation.

*Work Group Consensus Statement*

In patients with history and physical examination findings consistent with lumbar disc herniation with radiculopathy, MRI is recommended as an appropriate, noninvasive test to confirm the presence of lumbar disc herniation.

*Grade of Recommendation: A*

In patients with history and physical examination findings consistent with lumbar disc herniation with radiculopathy, CT scan, myelography and/or CT myelography are recommended as appropriate tests to confirm the presence of lumbar disc herniation.

*Grade of Recommendation: A*

Electrodiagnostic studies may have utility in diagnosing nerve root compression though lack the ability to differentiate between lumbar disc herniation and other causes of nerve root compression. When the diagnosis of lumbar disc herniation with radiculopathy is suspected, it is the work group's opinion that cross-sectional imaging be considered the diagnostic test of choice and electrodiagnostic studies should only be used to confirm the presence of comorbid conditions.

*Work Group Consensus Statement*

Somatosensory evoked potentials are suggested as an adjunct to cross-sectional imaging to confirm the presence of nerve root compression but are not specific to the level of nerve root compression or the diagnosis of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: B*

Electromyography, nerve conduction studies and F-waves are suggested to have limited utility in the diagnosis of lumbar disc herniation with radiculopathy. H-reflexes can be helpful in the diagnosis of an S1 radiculopathy, though are not specific to the diagnosis of lumbar disc herniation.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against the use of thermal quantitative sensory testing or liquid crystal thermography in the diagnosis of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of motor evoked potentials or extensor digitorum brevis reflex in the

diagnosis of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

Medical/Interventional Treatment

*What is the role of pharmacological treatment in the management of lumbar disc herniation with radiculopathy?*

Tumor necrosis factor (TNF) alpha inhibitors are not suggested to provide benefit in the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against the use of a single infusion of intravenous (IV) glucocorticosteroids in the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of 5-hydroxytryptamine (5-HT) receptor inhibitors in the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of gabapentin in the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of agmatine sulfate in the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of amitriptyline in the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*What is the role of physical therapy/exercise in the treatment of lumbar disc herniation with radiculopathy?*

There is insufficient evidence to make a recommendation for or against the use of physical therapy/structured exercise programs as stand-alone treatments for lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

In the absence of reliable evidence, it is the work group's opinion that a limited course of structured exercise is an option for patients with mild to moderate symptoms from lumbar disc herniation with radiculopathy.

*Work Group Consensus Statement*

*What is the role of spinal manipulation in the treatment of lumbar disc herniation with radiculopathy?*

Spinal manipulation is an option for symptomatic relief in patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: C*

There is insufficient evidence to make a recommendation for or against the use of spinal manipulation as compared with chemonucleolysis in patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*What is the role of traction (manual or mechanical) in the treatment of lumbar disc herniation with radiculopathy?*

There is insufficient evidence to make a recommendation for or against the use of traction in the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence*)

*What is the role of contrast-enhanced, fluoroscopic guidance in the routine performance of epidural steroid injections for the treatment of lumbar disc herniation with radiculopathy?*

Contrast-enhanced fluoroscopy is recommended to guide epidural steroid injections to improve the accuracy of medication delivery.

*Grade of Recommendation: A*

*What is the role of epidural steroid injections (ESI) for the treatment of lumbar disc herniation with radiculopathy?*

Transforaminal epidural steroid injection is recommended to provide short-term (2–4 weeks) pain relief in a proportion of patients with lumbar disc herniations with radiculopathy.

*Grade of Recommendation: A*

Interlaminar epidural steroid injections may be considered in the treatment of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: C*

There is insufficient evidence to make a recommendation for or against the 12 month efficacy of transforaminal epidural steroid injection in the treatment of patients with lumbar disc herniations with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*Is there an optimal frequency or quantity of injections for the treatment of lumbar disc herniations with radiculopathy?*

No evidence to address this question.

*Does the approach (interlaminar, transforaminal, caudal) influence the risks or effectiveness of epidural steroid injections in the treatment of lumbar disc herniations with radiculopathy?*

There is insufficient evidence to make a recommendation for or against the effectiveness of one injection approach over another in the delivery of epidural steroids for patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*What is the role of interventional spine procedures such as intradiscal electrothermal annuloplasty (IDEA) or intradiscal electrothermal therapy (IDET) and percutaneous discectomy (chemical or mechanical) in the treatment of lumbar disc herniation with radiculopathy?*

Note: For the purpose of this guideline, the work group defined the following interventional spine procedures addressed in this clinical question:

- Percutaneous discectomy is defined as any discectomy procedure that does not require open dissection of the thoracolumbar fascia. This includes endoscopic discectomy.
- Endoscopic percutaneous discectomy is defined as a discectomy procedure in which access to the disc herniation is made with a portal, visualization of the discectomy is done with an endoscope, and removal of disc material is done with micro instruments or laser. This is an indirect visualization technique using the endoscope and fluoroscopic guidance.
- Automated percutaneous discectomy is defined as a discectomy procedure in which a cannula is inserted into the intervertebral disc space, usually with fluoroscopic guidance, and nuclear material is removed without direct visualization by nucleotome, laser or radiofrequency heat. This is an indirect visualization technique using the endoscope and fluoroscopic guidance.

There is insufficient evidence to make a recommendation for or against the use of intradiscal ozone in the treatment of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

Endoscopic percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: C*

Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy in the treatment of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: B*

Automated percutaneous discectomy may be considered for the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: C*

There is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy in the treatment of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of plasma disc decompression/nucleoplasty in the treatment of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of plasma disc decompression as compared with transforaminal epidural steroid injections in patients with lumbar disc herniation who have previously failed transforaminal epidural steroid injection therapy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of intradiscal high-pressure saline injection in the treatment of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of percutaneous electrothermal disc decompression in the treatment of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*What is the role of ancillary treatments such as bracing, electrical stimulation, acupuncture and transcutaneous electrical stimulation (TENS) in the treatment of lumbar disc herniation with radiculopathy?*

There is insufficient evidence to make a recommendation for or against the use of ultrasound or low power laser in the treatment of lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*What is the likelihood that a patient with lumbar disc herniation with radiculopathy undergoing medical/interventional treatment would have good/excellent functional outcomes at short (weeks–six months), medium (six months–two years) and long-term (greater than two years)?*

Medical/interventional treatment is suggested to improve functional outcomes in the majority of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: B*

Transforaminal epidural steroid injections are suggested to improve functional outcomes in the majority of patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against the use of spinal manipulation to improve functional outcomes in patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*Are there prognostic factors (e.g., age, duration or severity of symptoms) that make it more likely that a patient with lumbar disc herniation with radiculopathy will have good/excellent functional outcomes at short (weeks–six months), medium (six months–two years) and long-term (greater than two years) following medical/interventional treatment?*

Patient age (under 40 years of age) and a shorter duration of symptoms (less than three months) are associated with better outcomes in patients

undergoing percutaneous endoscopic lumbar discectomy.

*Level of Evidence: II*

It is suggested that the type of lumbar disc herniation does not influence outcomes associated with transforaminal epidural steroid injections in patients with lumbar disc herniation with radiculopathy.

*Level of Evidence: II/III*

It is suggested that a higher degree of nerve root compression negatively affects outcomes associated with transforaminal epidural steroid injections in patients with lumbar disc herniation with radiculopathy.

*Level of Evidence: II/III*

There is insufficient evidence to make a recommendation regarding the influence of patient age on outcomes associated with medical/interventional treatment for patients with lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*What is the cost-effectiveness of medical/interventional treatment options in the management of lumbar disc herniation with radiculopathy?*

The methodology for assessing level of evidence for studies of cost-effectiveness is not well-defined.

Surgical Treatment

*Are there signs or symptoms associated with lumbar radiculopathy that predict a favorable surgical outcome?*

It is suggested that patients be assessed preoperatively for signs of psychological distress, such as somatization and/or depression, prior to surgery for lumbar disc herniation with radiculopathy. Patients with signs of psychological distress have worse outcomes than patients without such signs.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against the duration of symptoms prior to surgery affecting the prognosis for patients with cauda equina syndrome caused by lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

It is suggested that patients be assessed using the preoperative straight leg raising test prior to surgery, as the presence of a positive straight leg raise test correlates with better outcomes from surgery for lumbar disc herniation with radiculopathy.

*Grade of Recommendation: B*

*What is the role of epidural steroid injections or selective nerve root blocks in diagnosis or patient selection for subsequent surgical treatment of a lumbar disc herniation with radiculopathy?*

No studies were available to directly address this question.

*When is the optimal timing for surgical intervention?*

Surgical intervention prior to six months is suggested in patients with symptomatic lumbar disc herniation whose symptoms are severe enough to warrant surgery. Earlier surgery (within six months–one year) is associated with faster recovery and improved long-term outcomes.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against urgent surgery for patients with motor deficits due to lumbar disc herniation with radiculopathy.

*Grade of Recommendation: I (Insufficient Evidence)*

*Does discectomy (with or without preoperative medical/interventional treatment) result in better outcomes (clinical or radiographic) than medical/interventional treatment for lumbar disc herniation with radiculopathy?*

Discectomy is suggested to provide more effective symptom relief than medical/interventional care for patients with lumbar disc herniation with

radiculopathy whose symptoms warrant surgical intervention. In patients with less severe symptoms, surgery or medical/interventional care appear to be effective for both short- and long-term relief.

*Grade of Recommendation: B*

In a select group of patients automated percutaneous lumbar discectomy (APLD) may achieve equivalent results to open discectomy, however, this equivalence is not felt to be generalizable to all patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Level of Evidence: II/III*

There is insufficient evidence to make a recommendation for or against the use of spinal manipulation as an alternative to discectomy in patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

*Are there clinical circumstances in which lumbar fusion is appropriate in the treatment of lumbar disc herniation with radiculopathy?*

There is insufficient evidence to make a recommendation for or against fusion for specific patient populations with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

*Is there a difference in outcome (clinical or radiographic) or complications between different surgical approaches in the treatment of a lumbar disc herniation with radiculopathy?*

When surgery is indicated, performance of sequestrectomy or aggressive discectomy is recommended for decompression in patients with lumbar disc herniation with radiculopathy since there is no difference in rates of reherniation.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against the performance of aggressive discectomy or sequestrectomy for the avoidance of chronic low back pain in patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

Use of an operative microscope is suggested to obtain comparable outcomes to open discectomy for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against the use of medial facetectomy to improve the outcomes for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the specific surgical approach for far lateral disc herniations in patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of tubular discectomy compared with open discectomy to improve the outcomes for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

Note: For purposes of this guideline, the work group defined tubular discectomy as a discectomy procedure in which a tubular retractor is used to access the herniation. This usually involves making a smaller incision than with a traditional open microdiscectomy procedure and involves direct visualization of the disc and or nerve roots by naked eye and or microscope/loupe magnification.

There is insufficient evidence to make a recommendation for or against the application of glucocorticoids, with or without fentanyl, for short-term perioperative pain relief following decompression for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

The application of glucocorticoids, with or without fentanyl, is not suggested to provide long-term relief of symptoms following decompression for

patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: B*

There is insufficient evidence to make a recommendation for or against the application of a fat graft following open discectomy for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the addition of Oxiplex/SP gel or ADCON-L to discectomy for patients with lumbar disc herniation with radiculopathy whose symptoms warrant surgery.

*Grade of Recommendation: I (Insufficient Evidence)*

*What are the medium-term (one to four years) and long-term (greater than four years) results of surgical management of lumbar disc herniation with radiculopathy?*

The performance of surgical decompression is suggested to provide better medium-term (one to four years) symptom relief as compared with medical/interventional management of patients with radiculopathy from lumbar disc herniation whose symptoms are severe enough to warrant surgery.

*Grade of Recommendation: B*

Surgical decompression provides long-term (greater than four years) symptom relief for patients with radiculopathy from lumbar disc herniation whose symptoms warrant surgery. It should be noted that a substantial portion (23%–28%) of patients will have chronic back or leg pain.

*Level of Evidence: IV*

*Is there a difference in outcome or complications between different sites of service for the surgical management of a lumbar disc herniation with radiculopathy?*

No studies were available to address this question.

Value of Spine Care

*What is the cost-effectiveness of surgical treatment options in the management of lumbar disc herniation with radiculopathy?*

See the discussion in the original guideline document.

*Does the surgical approach for lumbar disc herniation with radiculopathy have an effect on the value of treatment?*

No studies were available to address this question.

*Does the site-of-service chosen for surgical management of lumbar disc herniation with radiculopathy affect the value of treatment?*

No studies were available to address this question.

Definitions:

Grades of Recommendation

A. Good evidence (Level I studies with consistent finding) for or against recommending intervention.

B. Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.

C. Poor quality evidence (Level IV or V studies) for or against recommending intervention.

I. Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Levels of Evidence for Primary Research Question[1]

| | Types of Studies | | | |
|---|---|---|---|---|
| | Therapeutic Studies – Investigating the results of treatment | Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease | Diagnostic Studies – Investigating a diagnostic test | Economic and Decision Analyses – Developing an economic or decision model |
| **Level I** | • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals<br>• Systematic review[2] of Level I RCTs (and study results were homogenous[3]) | • High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients)<br>• Systematic review[2] of Level I studies | • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)<br>• Systematic review[2] of Level I studies | • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses<br>• Systematic review[2] of Level I studies |
| **Level II** | • Lesser quality RCT (e.g., <80% follow-up, no blinding, or improper randomization)<br>• Prospective[4] comparative study[5]<br>• Systematic review[2] of Level II studies or Level 1 studies with inconsistent results | • Retrospective[6] study<br>• Untreated controls from an RCT<br>• Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up)<br>• Systematic review[2] of Level II studies | • Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)<br>• Systematic review[2] of Level II studies | • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses<br>• Systematic review[2] of Level II studies |
| **Level III** | • Case control study[7]<br>• Retrospective[6] comparative study[5]<br>• Systematic review[2] of Level III studies | • Case control study[7] | • Study of nonconsecutive patients; without consistently applied reference "gold" standard<br>• Systematic review[2] of Level III studies | • Analyses based on limited alternatives and costs; and poor estimates<br>• Systematic review[2] of Level III studies |
| **Level IV** | • Case series[8] | • Case series | • Case-control study<br>• Poor reference standard | • Analyses with no sensitivity analyses |
| **Level V** | • Expert opinion | • Expert opinion | • Expert opinion | • Expert opinion |

RCT = randomized controlled trial

[1] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

[2] A combination of results from two or more prior studies.

[3] Studies provided consistent results.

[4] Study was started before the first patient enrolled.

[5] Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.

[6] The study was started after the first patient enrolled.

[7] Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

[8] Patients treated one way with no comparison group of patients treated in another way.

Linking Levels of Evidence to Grades of Recommendation

| Grade of Recommendation | Standard Language | Levels of Evidence | |
|---|---|---|---|
| **A** | Recommended | Two or more consistent Level I studies | |
| **B** | Suggested | One Level I study with additional supporting Level II or III studies | Two or more consistent Level II or III studies |
| **C** | May be considered; is an option | One Level I, II or III study with supporting Level IV studies | Two or more consistent Level IV studies |
| I (Insufficient or Conflicting Evidence) | Insufficient evidence to make recommendation for or against | A single Level I, II, III or IV study without other supporting evidence | More than one study with inconsistent findings* |

* Note that in the presence of multiple consistent studies, and a single outlying, inconsistent study, the Grade of Recommendation will be based on the level of the consistent studies.

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Lumbar disc herniation with radiculopathy

Note: For the purposes of this guideline, lumbar disc herniation with radiculopathy is defined as localized displacement of disc material beyond the normal margins of the intervertebral disc space resulting in pain, weakness or numbness in a myotomal or dermatomal distribution.

## Guideline Category

Diagnosis

Evaluation

Management

Treatment

## Clinical Specialty

Anesthesiology

Chiropractic

Family Practice

Neurological Surgery

Orthopedic Surgery

Physical Medicine and Rehabilitation

Radiology

Surgery

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Managed Care Organizations

Nurses

Physical Therapists

Physician Assistants

Physicians

Utilization Management

## Guideline Objective(s)

- To provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of lumbar disc herniation with radiculopathy
- To reflect contemporary treatment concepts for symptomatic lumbar disc herniation with radiculopathy as reflected in the highest quality clinical literature available on this subject as of July 2011
- To assist in delivering optimum, efficacious treatment and functional recovery from this spinal disorder
- To provide an educational tool that assists practitioners in improving the quality and efficiency of care delivered to these patients

## Target Population

Adults (18 years or older) with a chief complaint of leg pain, numbness or weakness in a dermatomal or myotomal distribution as a result of a primary lumbar disc herniation

## Interventions and Practices Considered

Diagnosis

1. History and physical examination
    - Manual muscle testing
    - Sensory testing
    - Supine straight leg raise
    - Lasegue's sign
    - Crossed Lasegue's sign
2. Imaging
    - Magnetic resonance imaging (MRI)
    - Computed tomography (CT)
    - CT myelography
    - Cross-sectional imaging
    - Somatosensory (as an adjunct to cross-sectional imaging)

Note: Other diagnostic tools considered but not recommended include: cough impulse test, Bell test, hyperextension test, femoral nerve stretch test, slump test, lumbar range of motion

or absence of reflexes.

Treatment

1. Tumor necrosis factor (TNF) alpha inhibitors (not suggested to provide benefit)
2. Limited course of structured exercise (mild to moderate symptoms)
3. Spinal manipulation
4. Epidural steroid injections (ESI) (transforaminal, interlaminar) guided by contrast-enhanced fluoroscopy
5. Intradiscal electrothermal annuloplasty (IDEA)
6. Intradiscal electrothermal therapy (IDET)
7. Endoscopic percutaneous discectomy
8. Automated percutaneous discectomy
9. Selective nerve root blocks
10. Surgery
    - Automated percutaneous lumbar discectomy (APLD)
    - Decompression

Note: Other treatment interventions considered but not recommended include: single infusion of intravenous (IV) glucocorticosteroids, 5-hydroxytryptamine (5-HT) receptor inhibitors, gabapentin, agmatine sulfate, amitriptyline, physical therapy/structured exercise programs as stand-alone treatments, spinal manipulation as compared with chemonucleolysis, intradiscal ozone, automated percutaneous discectomy compared with open discectomy, plasma disc decompression/nucleoplasty, intradiscal high-pressure saline injection, percutaneous electrothermal disc decompression, ultrasound or low power laser, and traction.

## Major Outcomes Considered

- Assessment of pain, functional and psychological outcomes as measured by:
    - Visual Analog Scale (VAS)
    - Oswestry Disability Index (ODI)
    - McGill Pain Scale and other pain measures
    - Low Back Pain Disability Questionnaire (DISQ)
    - Numeric Pain Rating Scale
    - Global Rating of Change (GROC)
    - Fear Avoidance Belief Questionnaire
    - Sciatic Bothersome Index
    - Kellner Rating
    - SF-36
    - Roland Morris Disability Questionnaire
    - Aberdeen Back Pain Scale
    - Patient-Specified Functional Outcome Scale
    - Nottingham Health Profile
    - Numeric Rating Scale
    - Beck Depression Score
    - Odom's criteria
- Use of other healthcare
- Duration of relief
- Rate of rescue treatment or surgery
- Medication use
- Self-reported recovery
- Patient satisfaction
- Walking distance
- Improvement of straight leg raise restriction
- Sick leave
- Range of trunk flexion
- Range of left and right straight leg raise
- Time required to complete activities of daily living (ADL)

# Methodology

## Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Identification of Clinical Questions

Trained guideline participants were asked to submit a list of clinical questions that the guideline should address. The lists were compiled into a master list, which was then circulated to each member with a request that they independently rank the questions in order of importance for consideration in the guideline. The most highly ranked questions, as determined by the participants, served to focus the guideline.

Identification of Work Groups

Multidisciplinary teams were assigned to work groups and assigned specific clinical questions to address. Because North American Spine Society (NASS) is comprised of surgical, medical and interventional specialists, it is imperative to the guideline development process that a cross section of NASS membership is represented on each group. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized.

Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, NASS has instituted a Literature Search Protocol (see Appendix E in the original guideline document) which has been followed to identify literature for evaluation in guideline development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search.

Specific search strategies, including search terms, parameters and databases searched, are documented in the technical report that accompanies this guideline (see the "Availability of Companion Documents" field).

Completion of the Literature Search

Once each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian, consistent with the Literature Search Protocol.

Following these protocols ensures that NASS recommendations (1) are based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. NASS maintains a search history in Endnote, for future use or reference.

Review of Search Results/Identification of Literature to Review

Work group members reviewed all abstracts yielded from the literature search and identified the literature they will review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members have identified the best research evidence available to answer the targeted clinical questions. That is, if Level I, II and or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

# Rating Scheme for the Strength of the Evidence

Levels of Evidence for Primary Research Question[1]

| | Types of Studies | | | |
|---|---|---|---|---|
| | Therapeutic Studies – Investigating the results of treatment | Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease | Diagnostic Studies – Investigating a diagnostic test | Economic and Decision Analyses – Developing an economic or decision model |
| **Level I** | • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals<br>• Systematic review[2] of Level I RCTs (and study results were homogenous[3]) | • High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients)<br>• Systematic review[2] of Level I studies | • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)<br>• Systematic review[2] of Level I studies | • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses<br>• Systematic review[2] of Level I studies |
| **Level II** | • Lesser quality RCT (e.g., <80% follow-up, no blinding, or improper randomization)<br>• Prospective[4] comparative study[5]<br>• Systematic review[2] of Level II studies or Level 1 studies with inconsistent results | • Retrospective[6] study<br>• Untreated controls from an RCT<br>• Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up)<br>• Systematic review[2] of Level II studies | • Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)<br>• Systematic review[2] of Level II studies | • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses<br>• Systematic review[2] of Level II studies |
| **Level III** | • Case control study[7]<br>• Retrospective[6] comparative study[5]<br>• Systematic review[2] of Level III studies | • Case control study[7] | • Study of nonconsecutive patients; without consistently applied reference "gold" standard<br>• Systematic review[2] of Level III studies | • Analyses based on limited alternatives and costs; and poor estimates<br>• Systematic review[2] of Level III studies |
| **Level IV** | • Case series[8] | • Case series | • Case-control study<br>• Poor reference standard | • Analyses with no sensitivity analyses |
| **Level V** | • Expert opinion | • Expert opinion | • Expert opinion | • Expert opinion |

RCT = randomized controlled trial

[1] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

[2] A combination of results from two or more prior studies.

[3] Studies provided consistent results.

[4] Study was started before the first patient enrolled.

[5] Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.

[6] The study was started after the first patient enrolled.

[7] Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

[8] Patients treated one way with no comparison group of patients treated in another way.

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Evidence Analysis

Members have independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence. In order to systematically control for potential biases, at least two work group members have reviewed each article selected and independently assigned levels of evidence to the literature using the North American Spine Society (NASS) levels of evidence. Any discrepancies in scoring have been addressed by two or more reviewers. The consensus level (the level upon which two-thirds of reviewers were in agreement) was then assigned to the article.

As a final step in the evidence analysis process, members have identified and documented gaps in the evidence to educate guideline readers about where evidence is lacking and help guide further needed research by NASS and other societies.

## Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

## Description of Methods Used to Formulate the Recommendations

Formulation of Evidence-based Recommendations and Incorporation of Expert Consensus

Work groups held face-to-face meetings to discuss the evidence based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus has been incorporated only where Level I–IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this guideline very clearly indicate that Level I–IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

Consensus Development Process

Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 ("extremely inappropriate") to 9 ("extremely appropriate"). Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted. After the recommendations were established, work group members developed the guideline content, addressing the literature which supports the recommendations.

## Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

A. Good evidence (Level I studies with consistent finding) for or against recommending intervention.

B. Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.

C. Poor quality evidence (Level IV or V studies) for or against recommending intervention.

I. Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

### Cost Analysis

Published cost analyses were reviewed (see Section IV-E, "Value of Spine Care" in the original guideline document).

### Method of Guideline Validation

External Peer Review

Internal Peer Review

### Description of Method of Guideline Validation

Submission of the Draft Guidelines for Review/Comment

Guidelines were submitted to the full Evidence-based Guideline Development Committee and the Research Council Director for review and comment. Revisions to recommendations were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

Submission for Board Approval

Once any evidence-based revisions were incorporated, the drafts were prepared for North American Spine Society (NASS) Board review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Accurate diagnosis and effective treatment of lumbar disc herniation with radiculopathy

### Potential Harms

- Diagnostic tests may lead to false positive or false negative results.
- Surgical complications and recurrent herniation.

## Qualifying Statements

### Qualifying Statements

- This guideline does not represent a "standard of care," nor is it intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside this guideline will sometimes be necessary. This guideline should not be seen as prescribing the type, frequency or duration of intervention. Treatment should be based on the individual patient's need and doctor's professional judgment. This document is designed to function as a guideline and should not be used as the sole reason for denial of treatment and services. This guideline is not intended to expand or restrict a health care provider's scope of practice or to supersede applicable ethical standards or provisions of law.
- This clinical guideline should not be construed as including all proper methods of care or excluding or other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

## Implementation of the Guideline

### Description of Implementation Strategy

These guidelines are developed for educational purposes to assist practitioners in their clinical decision-making processes. It is anticipated that where evidence is very strong in support of recommendations, these recommendations will be operationalized into performance measures.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

North American Spine Society (NASS). Clinical guidelines for diagnosis and treatment of lumbar disc herniation with radiculopathy. Burr Ridge (IL): North American Spine Society (NASS); 2012. 100 p. [446 references]

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2012

## Guideline Developer(s)

North American Spine Society - Medical Specialty Society

## Source(s) of Funding

North American Spine Society (NASS)

## Guideline Committee

North American Spine Society (NASS) Evidence-based Clinical Guidelines Committee

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## Financial Disclosures/Conflicts of Interest

Disclosure of Potential Conflicts of Interest

All participants involved in guideline development have disclosed potential conflicts of interest to their colleagues and their potential conflicts have been documented in the guideline (see the "Financial Statement" in the original guideline document). Participants have been asked to update their disclosures regularly throughout the guideline development process.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: in Portable Document Format (PDF) from the North American Spine Society (NASS) Web site .

Print copies: Available from the North American Spine Society (NASS), 7075 Veterans Boulevard, Burr Ridge, IL 60527; Toll-free: (866) 960-6277. An order form is available from the North American Spine Society Web site .

## Availability of Companion Documents

The following is available:

- Diagnosis and treatment of lumbar disc herniation with radiculopathy. Technical report. Burr Ridge, IL: North American Spine Society, 2012. 212 p. Electronic copies: Available in Portable Document Format (PDF) from the North American Spine Society (NASS) Web site .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on July 12, 2013. This summary was updated by ECRI Institute on July 3, 2014 following the U.S. Food and Drug Administration advisory on Epidural Corticosteroid Injection. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines.

## Copyright Statement



# Disclaimer

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